EXHIBIT J

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May 11, 2023

CONTAINS MATERIAL MODERNA DESIGNATED HIGHLY CONFIDENTIAL – ATTORNEY'S EYES ONLY

Via Email

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Re: *Arbutus Biopharma Corporation and Genevant Sciences GmbH v. Moderna, Inc. and ModernaTX, Inc.*, Case 1:22-cv-00252-MSG (D. Del.)

Dear Mark:

Thank you for meeting and conferring with us regarding Plaintiffs' March 3, 2023 letter and for meeting and conferring on March 8, March 14, March 20, March 22, March 29, April 3, April 4, April 7, April 11, and April 12, 2023 regarding Moderna's RFP responses. We write to memorialize the parties' discussions on the deficiencies in those responses. Please provide Moderna's response to this letter and Plaintiffs' March 3, 2023 letter by May 19, 2023.

MODERNA'S REGULATORY SUBMISSIONS

For months, Plaintiffs have repeatedly asked Moderna to produce its BLA and core technical documents, to no avail. In multiple meet-and-confers, Moderna's only excuse for having not yet produced its complete BLA was a vague reference to the size of the BLA and difficulty in producing it. Moderna's April 18, 2023 production letter purported to constitute a "BLA Production," but it is unclear to Plaintiffs whether Moderna is representing that it now has produced its complete BLA. Please confirm whether Moderna has produced its complete BLAIf Moderna has not yet completed production of its BLA—including all associated communications with the FDA concerning its BLA—please confirm that Moderna will do so and provide a date certain for that production. Please also confirm when Moderna will produce its other regulatory submissions, including its complete IND and EUA, and other communications with the FDA.

Moderna has had months to produce its BLA and other regulatory documents and submissions. but has not done so.

Additionally, Plaintiffs' May 3, 2023 email identified an issue with Moderna's confidentiality designations of its BLA, which Moderna appears to have designated across-the-board as HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY, notwithstanding Moderna's representation that it would be designating confidentiality on a document-by-document basis based on alleged trade-secrets. Moderna has not responded to that email nor resolved the issue with its blanket designation; please provide Moderna's response and confirm that Moderna will re-produce its BLA with proper confidentiality designations. *See, e.g.*, MRNA-GEN-00141329 (designating Moderna's logo as HIGHLY CONFIDENTIAL).

MODERNA'S OBJECTIONS TO PLAINTIFFS' REQUESTS

***Third-parties* (*Objections 3 and 7*).** As explained in Plaintiffs' March 3, 2023 letter and our meet-and-confers, the involvement of third-party contractors in the development of Moderna's manufacturing processes is extensive and public. During our meet-and-confers, Moderna provided no response to inquiries in Plaintiffs' March 3, 2023 letter regarding Moderna's legal right to documents reflecting such third-party development work. Instead, Moderna pivoted to its demand that Plaintiffs agree to produce third-party documents, including documents subject to obligations of confidentiality to third-parties. Plaintiffs disagree that the parties are necessarily similarly situated with respect to the relevance and burden of producing third-party documents, including because the relevant third-parties appear to have been working *for* Moderna on the accused vaccine product (which presumably should entitle Moderna to the documents reflecting that work).

Regardless, however, Moderna's tit-for-tat approach to its discovery obligations—one that Moderna repeatedly proposed on our meet-and-confers—is improper. With respect to third-party issues, and in general, Moderna is required to perform its own investigation regarding relevant and responsive material that it is obligated to produce to Plaintiffs under the Federal Rules. *See, e.g..*, *McCoy c. SC Tiger Manor LLC*, 2021 WL 1326302, at *4 (M.D. La. Apr. 8, 2021) ("A party may not refuse to comply with an opposing party's discovery requests 'simply because [s]he believes that the opposing parties have not fully complied with [her] discovery requests to them.'"); *Lopez v. Don Herring Ltd.*, 327 F.R.D. 567, 580 (N.D. Tex. 2018); *Genentech, Inc. v. Trustees of Univ. of Pa.*, 2011 WL 7074208, at *1 (N.D. Cal. June 10, 2011) ("'The Court does not look favorably upon a 'tit-for-tat' approach to discovery. A party may not withhold relevant discovery simply on the basis that the other side has not been forthcoming with discovery.' 'A party may not excuse its failure to comply with discovery obligations by claiming that its opposing party is similarly delinquent. Nor may a party condition its compliance with its discovery obligations on receiving discovery from its opponent.'"); *Richardson v. City of Antioch*, 2009 WL 982118, at *1 (N.D. Cal. Apr. 13, 2009); *Fresenius Med. Care Holding Inc. v. Baxter Int'l, Inc.*, 224 F.R.D. 644, 652 (N.D. Cal. 2004); *Brown v. Bridges*, 2015 WL 410062, at *8 (N.D. Tex. Jan. 30, 2015); *Harris v. Commn'r Gary Lanigan*, 2016 WL 3626524, at *2 (D.N.J. July 1, 2016) ("[T]here is no place for "tit-for-tat" in a court of law."). Please confirm that Moderna will produce responsive third-party documents as requested in Plaintiffs' March 3, 2023 letter, and that Moderna will produce such responsive documents—including batch records, certificates of analysis, and manufacturing and

duplicative documents. If Moderna refuses to provide such confirmation, Plaintiffs will consider the parties to be at an impasse on this issue.

Products "not accused of infringement," pipeline products, PVU, and "platform process" (Objection 10). We understand from our meet-and-confers that Moderna is not limiting its production to documents that only reflect final versions of the Accused Product or final finished drug products, and will produce documents reflecting developmental versions as well as intermediate and/or non-final products. As explained in Plaintiffs' March 3, 2023 letter, Moderna's reliance on "pipeline" products, or its "PVU" or "platform process" in the research and development of the Accused Product, renders documents concerning these subjects relevant and responsive to this case. Please confirm that Moderna will produce these documents.

Government sales (Objection 20). We understand from our meet-and-confers that Moderna is not standing on its objection, and will not withhold documents concerning sales to the U.S. Government. Please confirm Plaintiffs' understanding.

Foreign infringing activity (Objection 21). With respect to Moderna's objection to producing information regarding "Accused Products not made, used, offered for sale, or sold within the United States or imported into the United States," Moderna agreed that in order for the Court (or even Plaintiffs) to assess Moderna's claims concerning allegedly "foreign" infringing activity, it would require Moderna to produce information regarding that foreign activity, including for instance, with respect to allegedly "foreign" batches or doses of the Accused Product. Moderna agreed to investigate whether it would produce such information. As requested in Plaintiffs' March 3, 2023 letter, please confirm that Moderna will not withhold information solely on the basis that it concerns allegedly "foreign" activity. If Moderna refuses to provide such confirmation, Plaintiffs will consider the parties to be at an impasse on this issue.

Safe harbor (Objection 22). We understand from our meet-and-confers that Moderna will not withhold documents "relating solely to batches and doses of the Accused Product subject to the safe harbor under 35 U.S.C. § 271(e)." Please confirm Plaintiffs' understanding.

GENERAL ISSUES

Search strategy. In response to Plaintiffs' concerns regarding the absence of information regarding Moderna's search strategy for responsive documents, Moderna stated that Plaintiffs' concerns would be addressed by Moderna's Paragraph 3 disclosures and the parties' ESI discovery protocol, which the parties are negotiating. Neither of these, however, address the issues that Plaintiffs raised in our March 3, 2023 letter. For example, they do not specify any date-range cutoffs that Moderna intends to employ. Moderna's RFP responses and disclosures also appear to omit lab notebooks. Please confirm that Moderna will supplement its RFP responses and that Moderna will search for and produce relevant lab notebooks.

Internal communications and documents. Plaintiffs' March 3, 2023 letter requested that Moderna confirm that it would produce internal documents and communications, including email and lab notebooks, in response to Moderna's omission of such documents in its responses to

RFP 53. Plaintiffs' March 3, 2023 letter identified that Moderna had only agreed to produce the -0100 Contract in response to this RFP seeking "any indemnification agreement or warranty between Defendants and any purchaser of the Accused Product." Moderna did not dispute the relevance of other agreements or warranties—but sought clarification as to whether Plaintiffs seek indemnification agreements and warranties for product liability. Plaintiffs confirmed that they do not seek such indemnification agreements and warranties for personal injury arising from the use of the Accused Product, but that indemnification agreements and warranties for infringement of intellectual property—including the patents-in-suit—are relevant. Moderna agreed to investigate the scope of other documents responsive to this request. Please confirm that Moderna will produce documents responsive to the full scope of this RFP.

RFP 54 (knowledge of USPTO and foreign patent office proceedings); RFP 55 (involvement in USPTO and foreign patent office proceedings). Moderna declined in its February 2, 2023 RFP responses to produce any documents in response to these RFPs. During our meet-and-confers, Moderna did not dispute the relevance of these documents with respect to at least Moderna's willful infringement, but instead sought Plaintiffs' reciprocal agreement to produce documents related to foreign patent office proceedings. For at least the reasons stated above, that is improper. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFPs 57, 58, and 59. Plaintiffs' March 3, 2023 letter identified that Moderna's responses to these RFPs excluded foreign licenses and licenses for LNP technology outside of the Accused Product. Moderna agreed to further investigate these other responsive documents. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFP 60 (agreements to develop, manufacture, sell, or distribute). Moderna declined in its February 2, 2023 RFP responses to produce any documents in response to this RFP. The only concern Moderna raised in our meet-and-confers with respect to this RFP was with respect to purportedly "foreign" agreements, which does not justify Moderna's wholesale refusal to produce documents responsive to this RFP. The nature of any burden on Moderna to produce "foreign" agreements is unclear to Plaintiffs, and in any event, such agreements are relevant at least to infringement and Moderna's apparent contention that certain batches of the Accused Product do not infringe because of an alleged "foreign" nexus. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFPs 61, 62, and 63. During our meet-and-confers, Moderna confirmed that it would produce the -0017 Contract in addition the -0100 Contract identified in its responses to these RFPs. As to other contracts, Moderna indicated that it was considering subject-matter limitations—to the extent that Moderna intends to apply such limitations, please identify them so that Plaintiffs can consider them. Moderna also agreed to further investigate its response to RFP 63 regarding agreements, contracts, grants, or licenses concerning funding from the U.S. Government relating to LNP therapeutics. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFPs 64 and 69. Plaintiffs' March 3, 2023 letter identified that Moderna had excluded internal documents and communications regarding its negotiations with the Government, and further limited the scope of relevant documents to "final executed agreements." As to internal documents and communications, Moderna conditioned its production of such documents on Plaintiffs' reciprocal agreement, which is improper for at least the reasons stated above. Moderna agreed to investigate producing documents concerning non-final draft agreements with the Government, as well as agreements with other third parties in response to RFP 69. Please confirm that Moderna will produce documents responsive to the full scope of this RFP.

RFPs 70 and 71 (Regulatory Submissions). With respect to RFPs 70 and 71, Plaintiffs' March 3, 2023 letter identified internal documents and communications as deficiencies in Moderna's responses. As explained above, during our meet and confers, Moderna conditioned its production of such documents on Plaintiffs' reciprocal agreement, which is improper for at least the reasons stated above. Additionally, with respect to foreign regulatory submissions, Plaintiffs have proposed a compromise that Moderna is investigating, as discussed above with respect to RFP 3. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFP 77. During our meet-and-confers, Moderna explained that in producing only "forward-looking forecasts," it was excluding historical forecasts from its production. As Plaintiffs explained, historical forecasts are also relevant to damages. Moderna agreed to investigate producing historical forecasts. Plaintiffs reiterate the relevance of historical forecasts, rather than merely historical data for past years. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFPs 80, 81, and 83 (sales and offers for sale). Moderna declined in its February 2, 2023 RFP responses to produce any documents in response to these RFPs. During our meet-and-confers, Moderna indicated that these RFPs were duplicative of other requests. Plaintiffs do not agree—for instance, while Moderna asserts that RFP 81 is duplicative of RFP 82, RFP 82 is directed to Moderna's *first* commercial offer for sale, while RFP 81 is not limited to such a *first* occurrence. *See* at Defendants' Objections and Responses to Plaintiffs' First Set of Requests for Production (Nos. 1–98) at 90. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFP 84. Plaintiffs' March 3, 2023 letter identified internal documents and communications as well as drafts of the studies, preprints, and other publications related to the Accused Product as documents sought by this RFP. During our meet-and-confers, Moderna did not dispute the relevance of the information sought, including with respect to the Corbett preprint. Moderna agreed to investigate these other documents. Please confirm that Moderna will produce documents responsive to the full scope of this RFP.

RFPs 85, 86, and 87 (COVID-19 and LNP patents). Moderna declined in its February 2, 2023 RFP responses to produce any documents in response to these RFPs. During our meet-and-confers, Moderna broadly challenged the relevance of the documents sought by these RFPs. These documents are relevant at least to Moderna's contention that the Accused Product "uses Moderna's

proprietary LNP delivery technology." *See, e.g.*, D.I. 35 ¶ 10. Moderna also conditioned its production of responsive documents on Plaintiffs' reciprocal agreement, which is improper for at least the reasons stated above. Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFPs 95 and 96 (Alnylam v. Moderna). Moderna declined in its February 2, 2023 RFP responses to produce any documents in response to these RFPs. During our meet-and-confers, Moderna purported to dispute the relevance of requested documents from *Alnylam*, but did not dispute that the accused product is the same or that the patent asserted in *Alnylam* is related to the LNP technology that is at issue here.[4] Moreover, Moderna specifically directed the *Alnylam* Court's attention to "subsequent developments" in this case, further underscoring the relevance of the information sought. No. 22-335-CFC, D.I. 56. Nor did Moderna on our meet-and-confers explain any burden associated with simply producing the requested documents. Indeed, substantial completion of document production in *Alnylam* is set for June 1, 2023, No. 22-335-CFC, D.I. 31 at 9, and Moderna did not dispute the absence of any significant burden associated with simply producing documents that have already been recently reviewed, redacted for privilege, and processed for production. Given the significant overlap in subject matter between this case and *Alnylam*, the requested documents are plainly relevant and proportional. *See, e.g.*, *Peterson v. Wright Medical Technology, Inc.*, 2013 WL 655527, at *5–6 (C.D. Ill. Feb. 21, 2013); *Whitman v. State Farm Ins. Co.*, 2020 WL 5526684, at *3 (W.D. Wash. Sept. 15, 2020). Please confirm that Moderna will produce documents responsive to the full scope of these RFPs.

RFPs 97, 98 (samples). As set forth in Plaintiffs' March 3, 2023 and April 28, 2023 letters, the parties require additional information to negotiate the scope of sample production, which information Moderna failed to provide in response to Plaintiffs' Interrogatories Nos. 6 and 11, and which Moderna has not provided to date. Please provide a date certain on when Moderna will supplement its responses to Plaintiffs' interrogatories, and your availability to meet and confer regarding sample production.

Sincerely,

Lydia B. Cash

cc: Counsel of Record

[4] Plaintiffs note, for instance, that Moderna has insisted on a prosecution bar in this case that encompasses "ionizable lipids for nucleic acid delivery." D.I. 91 at 16.